

REMARKS

Group Election

In the Office Action dated January 17, 2007, the Examiner has issued a restriction requirement, identifying the following three Groups;

Group I: claims 1-47, 49-55, and 57-60 drawn to drug delivery conjugates  
Group II: claims 48 and 56 drawn to methods of eliminating pathogenic cells  
Group III: claims 61-63 drawn to processes for making the compounds of independent claims 61 and 62.

The Examiner considers the inventions defined by the delineated Groups to be distinct. Applicants traverse this restriction requirement and consider that the three Groups do not represent distinct inventions for the reasons given below.

The Examiner, relying on MPEP § 806.05(h), states that the inventions defined by Groups I and II are distinct from each other because “the methods of elimination of a population of pathogenic cells in a host animal as set forth in independent claims 48 and 56 may be utilized with any of the compounds of Group I disclosed in independent claims 1, 49, 51, 52, and 57” (page 2, emphasis added). In addition, the Examiner, relying on MPEP § 806.05(f), states that the inventions defined by Groups I and III are distinct from each other because “the process for making the compounds of Group II [*sic*, Group I] may be used to make other vitamin containing products encompassed by Group I (page 3, emphasis added).

Applicants respectfully suggest that the Examiner has misunderstood the cited sections of the MPEP and therefore believe that the restriction of the pending claims into Groups I, II, and III is improper. Regarding the distinction made by the Examiner for Groups I and II, the relevant portion of MPEP § 806.05(h), quoted by the Examiner in the Office action, states:

(A) the process of using as claimed can be practiced with another materially different product ....

(MPEP § 806.05(h), emphasis added). Claims 48 and 56 each recite a method for “eliminating a population of pathogenic cells in a host animal” and each of claims 48 and 56 depend from claim 1. Claim 1 recites a specific vitamin receptor binding drug delivery conjugate comprising “(a) a vitamin receptor binding moiety; (b) a bivalent linker; and (c) a drug, or an analog or derivative thereof.” Therefore, Applicants argue that claim 1 and claims 48 and 56 are not distinct as suggested by the Examiner. In fact, the Examiner’s articulation of the rule in MPEP § 806.05(h) is consistent with Applicants’ position. The Examiner states that the methods recited in claims 48 and 56 “may be used to make other

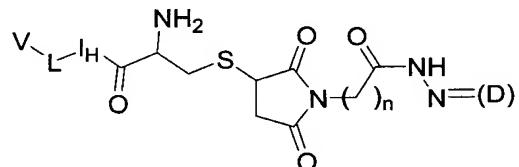
vitamin containing products encompassed by Group I.” Therefore, because the claimed methods cannot be used with materially different products than those recited in claim 1, i.e. pursuant to MPEP § 806.05(h) the invention of Group I “can[not] be practiced with another materially different product,” the inventions of Groups I and II are not distinct.

Further, it is clear from the dependency of claim 48 and 56 on base claim 1, that insofar as the recited conjugates are concerned in each of Groups I and II, the claims are coextensive. Thus, a proper search and examination of the claims in Group I will be equally applicable to those in Group II, because once the conjugates of Group I are found to be patentable, it follows that the method claims, which are dependent therefrom and thus cannot be any broader than claim 1, must also be patentable. Accordingly, Applicants request reconsideration of the restriction requirement between Group I (including claims 1-47, 49-55, and 57-60) and Group II (including claims 48 and 56) as being improper, and request its withdrawal.

Regarding the distinction made by the Examiner for Groups I and III, the relevant portion of MPEP § 806.05(f), quoted by the Examiner in the Office action, states:

(A) ... the process *as claimed* can be used to make another materially different product....

(MPEP § 806.05(f), emphasis in original). Claims 61-63 each recite a process for preparing a compound of the formula:



where V is a vitamin receptor binding moiety; L is selected from the group consisting of (l<sub>r</sub>)<sub>c</sub>, (l<sub>s</sub>)<sub>a</sub>, and (l<sub>H</sub>)<sub>b</sub>, and combinations thereof, where (l<sub>r</sub>) is a releasable linker, (l<sub>s</sub>) is a spacer linker, (l<sub>H</sub>) is an heteroatom linker, and a, b, and c are integers selected from the group consisting of 0, 1, 2, 3, and 4; and D is a drug, or an analog or a derivative thereof; ....

(claim 61). The recited formula represents a subset of compounds falling within the scope of vitamin receptor binding drug delivery conjugates claimed in claim 1. Therefore, Applicants argue that claim 1 and claims 61-63 are not distinct as suggested by the Examiner.

Applicants therefore suggest that the Examiner has misread Applicants’ claims 61-63. Contrary to the Examiner’s reading, claims 61-63 are not drawn to processes of making “other vitamin containing products encompassed by Group I.” Therefore, because claims 61-

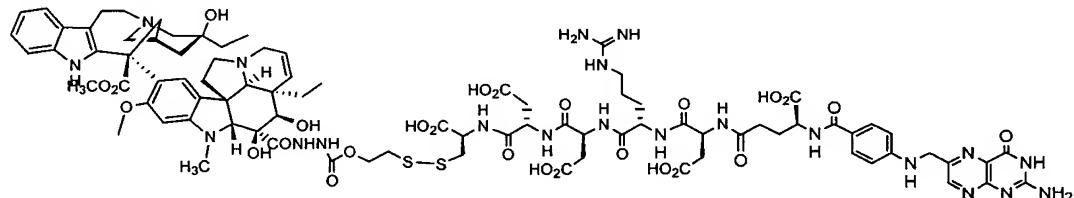
63 recite a process for making only a subset of compounds recited in claim 1, Applicants' invention "*as claimed* can[not] be used to make another materially different product" (emphasis in original), and thus does not fall within the set of circumstances for a proper restriction requirement under MPEP § 806.05(f).

Further, it is clear that because claims 61-63 recite only a subset of those compounds recited in claim 1, insofar as the recited conjugates are concerned in each of Groups I and III, a proper search and examination of the claims in Group I will be equally applicable to those in Group III. This is so because once the conjugates of Group I are found to be patentable, it follows that the process claims, which are narrower at least in one respect than the product claims, must also be patentable. Accordingly, Applicants request reconsideration of the restriction requirement between Group I (including claims 1-47, 49-55, and 57-60) and Group III (including claims 61-63) as being improper, and request its withdrawal.

Should the Examiner nevertheless maintain the restriction requirement, despite Applicants' arguments to the contrary, Applicants elect herein Group I.

Election of species under 37 C.F.R. § 1.146

The Examiner has also required Applicants to elect a single disclosed species in Group I. Accordingly, Applicants elect herein the species described in Example 1b, namely the compound of the following formula:



where as indicated, the vitamin receptor binding moiety is folate, the bivalent linker comprises the tetrapeptide Asp-Arg-Asp-Asp-Cys and the radical  $-S(CH_2)_2-OC(O)-$ ; and the drug is desacetylvinblastine monohydrazone. To facilitate this phase of the prosecution of the claims in Group I, Applicants have amended the pending claims to include sub-genus claims 64-65. Support for this amendment is found throughout the specification, and in particular in Examples 16b and 17a of the application as filed. Accordingly, claims 1-4, 7, 16-19, 34, 37-38, 41, 47, 51-52, 55, 64-65 are readable on the elected species. Further, should the Examiner withdraw the restriction requirement and maintain the election of

species, Applicants respectfully point out that claims 48 and 56 in unelected Group II are also readable on the elected species.

Applicants believe that the claims are in condition for allowance, and respectfully request that the application be passed to issue.

Respectfully submitted,  
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